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20

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09/703,518	10/31/2000	Jessica G. Chiu	ACSC-60042	1874

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EXAMINER	
PHANIJPHAND, GWEN G	
ART UNIT	**PAPER NUMBER**
3731	9

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/703,518	CHIU ET AL.	
	Examiner	Art Unit	
	Gwen Phanijphand	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO AMENDMENT

Amendment

On page 14 of the amendment, "21" should be numbered "23, since it is claim 23 that has been amended.

Claim Rejections – 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that he subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made

1. Claims 1, 3, 4, 9, 11, 12, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,797,868 to Leone.

Regarding claim 1, Leone discloses a catheter, having a polymeric component (a balloon: col. 3, ll. 33-36) having a radiopaque marker (col. 4:44-45, 51-52: "titanium dioxide" and "silver" being radiopaque materials), comprising a first layer of radiopaque material but does not disclose a second layer of radiopaque material on the first layer with the second layer of radiopaque material having a thickness greater than a thickness of the first layer. It would have been obvious to one having ordinary skill in the art at the time of the invention that multiple thin layers can combine to create one thick layer. Hence, if four thin layers are deposited, the first thin layer could comprise the first layer and the second through fourth thin layers could form one thicker layer, comprising the second layer. Thus, the second layer would have a thickness greater than that of the first layer.

Regarding claim 3, Leone discloses that the second layer of radiopaque material can extend the entire length of the first layer. The first layer coats the balloon, and thus if the first layer is continually deposited, a second layer entirely coats the first layer.

Regarding claim 4, Leone discloses the first and second layers of radiopaque material formed of the same radiopaque material (col. 4, ll. 44-45, 51-52: "titanium dioxide" and "silver"). It is inherent that the titanium dioxide and silver coating can be continually deposited until there is a second layer of the same material on the first layer.

Regarding claim 9, Leone discloses in Fig. 3 the catheter wherein the polymeric catheter component comprises a first section longitudinally spaced from a second section adjacent thereto (elements 12 and 29, shown in Fig. 1), and the first layer of radiopaque material (25b) is joined to and extends between the longitudinally spaced sections. In Fig. 4, the radiopaque material (25c) also extends between two adjacent sections.

Regarding claim 11, Leone discloses the polymeric catheter component being an inflatable balloon (col. 5, ll. 12-17).

Regarding claim 12, Leone discloses a distal radiopaque marker at a distal and proximal end of the working length of the balloon (Fig. 3, 25b and Fig. 4, 25c) and the proximal and distal radiopaque markers each comprising a first layer of radiopaque material. Leone, however, does not disclose a second layer of radiopaque material on the first layer, having a thickness greater than the thickness of the first layer. It would have been obvious to one having ordinary skill in the art at the time of the invention that multiple thin layers can combine to create one thick layer. Hence, if four thin layers are deposited, the first thin layer could comprise the first layer and the

second through fourth thin layers could form one thicker layer, comprising the second layer. Thus, the second layer would have a thickness greater than that of the first layer.

Regarding claim 17, Leone discloses in Figs. 1 and 4 a balloon catheter (col. 5, ll.12-17) comprising an elongated catheter shaft, a balloon on a distal section of the catheter having a working length (29), and at least one radiopaque marker on the surface of the working length of the balloon (col. 5, ll.12-15). The radiopaque marker (25c) does not cover the entire length of the working length of the balloon in Fig. 4.

Regarding claim 18, Leone discloses the catheter comprising at least one distal radiopaque marker on the distal end of the working length of the balloon (Fig. 3, 25b) and a proximal radiopaque marker on the proximal end of the working length of the balloon (Fig. 4, 25c). Leone further discloses a first layer of radiopaque material but does not disclose a second layer of radiopaque material on the first layer, having a thickness greater than a thickness of the first layer. It would have been obvious to one having ordinary skill in the art at the time of the invention that multiple thin layers can combine to create one thick layer. Hence, if four thin layers are deposited, the first thin layer could comprise the first layer and the second through fourth thin layers could form one thicker layer, comprising the second layer. Thus, the second layer would have a thickness greater than that of the first layer.

2. Claims 1-8, 11, 13, 14, 15, and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,873,904 to Ragheb et al.

Regarding claim 1, Ragheb et al. disclose a catheter, having a polymeric component (col. 3, ll. 51-53, ll. 58-65: polymer "stent") having a radiopaque marker (Fig. 4: element 18; col. 3, ll. 60-63: "silver" or col. 10, ll. 58-60, col. 11, ll. 22-25: "gold, tantalum, platinum"). Ragheb

further discloses a second layer coating the first layer (col. 9, ll. 26-29; col. 14, ll. 42-48). Raheb et al., however, do not disclose a second layer of radiopaque material on the first layer, having a thickness greater than a thickness of the first layer. It would have been obvious to one having ordinary skill in the art at the time of the invention that multiple thin layers can combine to create one thick layer. Hence, if four thin layers are deposited, the first thin layer could comprise the first layer and the second through fourth thin layers could form one thicker layer, comprising the second layer. Thus, the second layer would have a thickness greater than that of the first layer.

Regarding claim 2, Ragheb et al. disclose the first layer of radiopaque material comprising a deposited layer of radiopaque material (col. 9, ll. 19-22) on an outer surface of the polymeric catheter component and the second layer of radiopaque material comprising an electroplated layer of radiopaque material on an outer surface of the first layer of radiopaque material (col. 3, ll. col. 9, ll. 19-29; col. 14, ll. 42-48).

Regarding claim 3, Ragheb et al. disclose that the second layer of radiopaque material can extend the entire length of the first layer. It is inherent that if the radiopaque material is continually applied after a first layer is completed, a second layer of the same radiopaque material will extend the entire length of the first layer (col. 3, ll. 49-65; col. 9, ll. 26-29).

Regarding claim 4, Ragheb et al. disclose the first and second layers of radiopaque material formed of the same radiopaque material (col. 10, ll. 58-60, col. 11, ll. 22-25: "gold, tantalum, platinum"; col. 14, ll. 42-48: layers 18 and 22).

Regarding claim 5, Ragheb et al. disclose the first layer of radiopaque material having a smaller particle size than the second layer of radiopaque material (col. 14, ll. 42-46, ll. 64-67:

first layer 18 and second layer 22). The second layer can comprise a radiopaque material that has smaller particle size than the first layer of radiopaque material.

Regarding claim 6, Ragheb et al. disclose that the first layer of radiopaque material can be of different material than the second layer of radiopaque material (col. 14, ll. 42-48).

Regarding claim 7, Ragheb et al. disclose the radiopaque material comprising a blend of a polymeric and radiopaque material (col. 4, ll.4-5; col. 9, ll. 1-25). Ragheb discloses that parylene, a polymeric material, can be within the coating (col. 21, ll. 59-67; col. 22, ll.1-2).

Regarding claim 8, Ragheb et al. disclose the second layer comprising an electroplated layer of radiopaque material on the blended first layer (col. 14, ll. 42-46, ll. 64-67; col. 21, ll. 59-62). The second layer, 22, can comprise of the same material as the first layer, 18.

Regarding claim 10, Ragheb et al. disclose the catheter wherein the polymeric catheter component (col. 25, ll. 16-32) is a catheter shaft (col. 1, ll. 20-26; col. 3, ll. 31-33). Ragheb discloses a catheter shaft as a medical device that can be treated with silver, a radiopaque material, for implantation

Regarding claim 11, Ragheb et al. disclose the polymeric catheter component being an inflatable balloon (col. 1, ll. 21-27; col. 3, ll. 40-44). Ragheb discloses that the catheter component can be an implantable medical device and lists a balloon as a device that can be treated (such as being coated by the radiopaque material, silver) for implantation into the body.

Regarding claim 13, Ragheb et al. disclose each of the distal and proximal radiopaque markers can have a length substantially less than a length of a working length of the balloon (col. 8, ll. 17-20; claim 9).

Regarding claim 14, Ragheb et al. disclose the thickness of the first layer being about 0.001 mm to about 0.01 mm (col. 21, ll. 50-53).

Regarding claims 15 and 25, Ragheb et al. disclose the thickness of the first layer being about 0.001 mm to about 0.01 mm but do not disclose the thickness of the second layer being about 0.02 mm to about 0.025 mm (col. 21, ll. 50-54). It would have been obvious to one having ordinary skill in the art at the time of the invention that multiple thin layers can combine and form one thicker, second layer. Hence, if three layers of about 0.001 mm to about 0.01 mm are deposited, the first layer of about 0.001 mm to about 0.01 mm is the first layer and the second and third layers combine to create one thick layer of about 0.02 mm to about 0.025 mm.

Regarding claim 19, Ragheb et al. disclose a method of making a radiopaque marker for a polymeric catheter component comprising depositing a first layer of radiopaque material onto at a last section of the polymeric catheter component and electroplating a second layer of radiopaque material onto an outer surface of the first layer of radiopaque material (col. 3, ll. 49-65; col.14, ll. 42-47). Ragheb discloses that only a portion of the catheter component can be coated (col. 8, ll. 17-20; claim 9), and hence it is inherent that the last section can be coated.

Regarding claim 20, Ragheb et al. disclose depositing the first layer by thin film deposition (col. 22, ll. 41- 43: "vapor deposition").

Regarding claim 21, Ragheb et al. disclose that the first layer is deposited by a thin film deposition technique selected from the group consisting of chemical vapor deposition and physical vapor deposition (22, ll. 41- 43).

Regarding claim 22, Ragheb et al. disclose depositing the first layer of radiopaque material onto a section of the catheter component having a length substantially less than the a

length of the catheter component (col. 8, ll. 17-20; claim 9). Ragheb discloses depositing a layer of radiopaque material only on a portion of the component.

Regarding claim 23, Ragheb et al. disclose the method wherein the polymeric catheter component is a balloon (col. 1, ll. 21-27; col. 3, ll. 40-44) and includes electroplating onto the first layer a second layer. Ragheb et al., however, do not disclose the second layer being a thicker layer of radiopaque material than the first layer of radiopaque material. It would have been obvious to one having ordinary skill in the art at the time of the invention that multiple thin layers can combine to create one thick layer. Hence, if four thin layers are deposited, the first thin layer could comprise the first layer and the second through fourth thin layers could form one thicker layer, comprising the second layer. Thus, the second layer would have a thickness greater than that of the first layer.

Regarding claim 24, Ragheb et al. disclose the catheter component being a catheter shaft with a second layer of radiopaque material electroplated onto the first layer (col. 1, ll. 20-26; col. 3, ll. 31-37, l. 55). Ragheb et al. disclose a catheter shaft as a medical device that can be treated with silver, a radiopaque material, for implantation. Ragheb et al. do not disclose a second layer of radiopaque material having a thickness greater than that of the first layer. It would have been obvious to one having ordinary skill in the art at the time of the invention that multiple thin layers can be electroplated onto the catheter shaft and combine to create one thick layer. Hence, if four thin layers are electroplated, the first thin layer could comprise the first layer and the second through fourth thin layers could form one thicker layer, comprising the second layer. Thus, the second layer would have a thickness greater than that of the first layer.

Regarding claim 26, Ragheb et al. disclose electroplating a layer of radiopaque material onto an outer surface of at least a section of a catheter component, comprising a blend of polymeric and radiopaque material (col. 3, ll. 55-60; col. 4, ll. 4-5; col. 9, ll. 1-25). Ragheb et al. disclose that parylene, a polymeric material, can be in the coating (col. 21, ll. 59-67; col. 22, ll.1-2).

3. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,873,904 to Ragheb et al. as applied to claims above.

Regarding claim 16, Ragheb et al. disclose the second layer but does not disclose that the length of the layer is about 0.05 mm to about 1.5 mm. It would have been an obvious matter of design choice to have the second layer be about 0.05 mm to about 1.5 mm, since such a modification would have involved a mere change in the size of a layer. A change in size is generally recognized as being within the level of ordinary skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

A stent and a balloon are considered components of a catheter, since these parts are often attached to the catheter. Ragheb also states that the structure to be coated can be "configured as at least one of, or any portion of, a catheter, a wire guide, a cannula, a stent, a vascular or other graft....(col. 8, ll. 20-22)."

Ragheb and Leone both disclose polymeric catheter components coated in radiopaque material (silver and titanium being well known radiopaque materials).

It is obvious that a coating can be continually deposited until there are multiple layers of that coating, and multiple layers can combine and form one thicker layer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP GP
May 1, 2003

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